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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,164	05/03/2001	Peter R. Rhode	46146-C2 (48340)	1034
21874	7590	08/25/2005	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			VANDERVEGT, FRANCOIS P	
			ART UNIT	PAPER NUMBER
			1644	
DATE MAILED: 08/25/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/848,164

Applicant(s)

RHODE ET AL.

Examiner

F. Pierre VanderVegt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 June 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 53-55, 57-63, 66-69 and 71-76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 66-69 and 71-76 is/are allowed.
- 6) ☒ Claim(s) 53-55 and 57-63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f):
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>05032001</u> . | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

This application is a continuation of U.S. Application Serial Number 09/067,615, which is a continuation of U.S. Application Serial Number 08/596,387.

Claims 1-52, 56, 64-65, 70 and 77-87 have been canceled.

Claims 53-55, 57-63, 66-69 and 71-76 are currently pending and are the subject of examination in the present Office Action.

In view of Applicant's amendment filed June 3, 2005, all outstanding grounds of rejection are withdrawn.

The following represents a new ground of rejection that necessitates this Office Action being made NON-FINAL.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 53-55, 57, 58 and 60-63 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a single chain MHC class II-peptide complex that is empty or where the presenting peptide is one that would be non-covalently bound by the MHC class II molecule such that the MHC/peptide complex can be recognized by a CD4+ T cell, does not reasonably provide enablement for a single chain MHC class II-peptide complex where the presenting peptide is not one that would be non-covalently bound by the peptide binding groove of the MHC class II. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

While the claims were previously indicated as being allowable, further review of the claims indicates that the claims should have been rejected under the same ground of rejection as claims 66-69 and 71-76. The claims are written in an open format not restricted to "empty" single chain MHC class II molecules and the claims still encompass the inclusion of a covalently bound presenting peptide as part of the molecule that is not one that would be non-covalently bound by the peptide binding groove of the MHC class II. Applicant's inclusion of a non-covalently bound peptide as being included with the

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recitation of “[t]h MHC molecule” in dependent claim 59 reinforces the view that a covalently bound presenting peptide is included within the scope of claim 53. It is suggested that claim 53 be amended to recite --consisting of--.

The claims are broadly drawn to single chain molecules wherein a single chain MHC class II molecule is covalently bound to a “presenting peptide.” The specification defines a “presenting peptide” as “a peptide that is capable of modulating the activity of a T cell receptor, either to induce T-cell proliferation, to inhibit or inactivate T cell development.” The claims do not require, however, that the peptide be presented in the context of an MHC class II molecule that normally binds that peptide and presents it to an antigen-specific CD4+ T cell.

In order for a compound to be enabled for the scope of a claim, the compound must be usable for the processes disclosed in the specification. The claimed single chain MHC class II peptide fusion complexes are disclosed in the specification at page 8, lines 4-14 (for example), as being useful for in vitro identification of peptides recognized by a T cell receptor, methods for suppressing an immune response, methods for inducing a desired immune response, and diagnostic methods such as HLA typing and in vivo diagnostic imaging.

It is well established in the art that CD4+ T cells specifically recognize presenting peptides in the context of a particular MHC class II heterodimer (see, for example, pages 291-293 of Germain *in Fundamental Immunology*, Fourth Edition; U on form PTO-892). It is further well known that MHC class II heterodimers specifically bind presenting peptides based upon the position of particular anchor residues within the sequence of the presenting peptide (pages 298, 300-301 and 303 for example).

The instant claims, however, are not limited to constructs comprising a presenting peptide that is specifically recognized by the single chain MHC class II molecule to which it is attached. Based upon the lack of guidance in the specification, the artisan would not be able to determine whether the presenting peptide of such a construct would be able identified as a peptide recognized by a T cell receptor because the peptide may not reside in the peptide binding groove of the MHC class II molecule and the T cell therefore would not be able to recognize the peptide in the context of that MHC class II molecule, although the T cell may be able to recognize the peptide in the context of another (properly matched) MHC class II molecule.

The artisan would not be able to predict that single chain MHC class II-peptide complexes of the invention would be able to suppress an immune response or induce a desired immune response because the peptide of the complex may not be properly associated with the MHC class II molecule to which it is bound. Furthermore, it would require undue experimentation on the part of the practitioner to perform

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diagnostic methods such as HLA typing and in vivo diagnostic imaging with single chain MHC class II-peptide complexes commensurate with the scope of the claims because the complex may not be properly oriented to serve as the detection reagents of the assay.

The present specification acknowledges that antigenic or presenting peptides must be associated with specific MHC class II molecules based upon non-covalent binding of the MHC class II molecule with particular anchor residues on the peptide (page 1, lines 22-25, and paragraph bridging pages 3-4 for example). The artisan would expect that the same type of association is required of a peptide that is covalently attached to a single-chain MHC class II molecule.

Accordingly, only single chain MHC class II-peptide complexes comprising a presenting peptide that is properly recognized by the single chain MHC class II molecule to which it is covalently bound are adequately enabled by the instant specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 59 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 59 recites the limitation "MHC molecule of claim 53 further comprising a presenting peptide non-covalently linked to a peptide binding groove of the MHC molecule." There is insufficient antecedent basis for this limitation in the claim. There is no antecedent basis for saying that the MHC molecule further comprises a non-covalently bound element because this is not part of the same molecule, rather it is complexed with that molecule. It is suggested that the claim be amended accordingly. For example --A MHC complex comprising the single chain MHC molecule of claim 53 and a presenting peptide non-covalently linked to a peptide binding groove of the MHC molecule.--

#### *Conclusion*

3. Claims 66-69 and 71-76 are allowed.
4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.  
Patent Examiner  
February 25, 2005

*RV*

*David A Saunders*  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 182-1644